OCT - 9 2001

K013295

**510(k) Summary**

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| SUBMITTER: | DePuy AcroMed, Inc.<br>325 Paramount Drive<br>Raynham, MA 02780 |
| CONTACT PERSON: | Lisa A. Gilman |
| DATE PREPARED: | August 28, 2001 |
| CLASSIFICATION NAME: | Appliance, Fixation, Spinal Interlaminal<br>Orthosis, Spinal Pedicle Fixation |
| PROPRIETARY NAME: | TIMX Spine System |
| PREDICATE DEVICES: | MOSS MIAMI Spinal System Transverse Connector (K983583)<br>EZ-Link Transverse Connector (K001372, K001470) |
| DEVICE DESCRIPTION: | The CrossOver Cross Connector is designed to transversely connect two rods used in spinal instrumentation constructs. The connector minimizes the torsional forces on the construct, thus reducing the micromotion and the probability of the construct shifting after placement. |
| INTENDED USE: | The TIMX Spine System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).<br><br>The TIMX Spine System is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. |

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| | The TIMX Spine System is also a hook and sacral/iliac screw fixation system of the noncervical spine indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis). |
| MATERIALS: | Manufactured from ASTM F-136 implant grade titanium alloy. |
| PERFORMANCE DATA: | Performance data were submitted to characterize the CrossOver Cross Connector. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 9 2001

Mr. Frank Maas
Manager, Regulatory Affairs
DePuy Acromed, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K013295
Trade/Device Name: TiMX Spinal System
Regulatory Number: 21 CFR 888.3070, 21 CFR 888.3070, 21 CFR 888.3050
Regulation Name: Pedicle Screw Spinal System, Spinal Interlaminal Fixation Orthosis, Spondylolisthesis Spinal Fixation Device System
Regulatory Class: II
Product Code: MNH, MNI, KWP
Dated: October 2, 2001
Received: October 2, 2001

Dear Mr. Maas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Susan Walthall

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known): K013295

Device Name: TIMX Spinal System

Indications For Use:

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The TIMX Spine System is also a hook and sacral/iliac screw fixation system of the noncervical spine indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013295